IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH,	)	
Plaintiffs,	)	
v.	)	C.A. No. 22-252 (MSG)
MODERNA, INC. and MODERNATX, INC.,	)	
Defendants.	)	

DEFENDANTS' REPLY BRIEF IN SUPPORT OF THEIR PARTIAL MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(B)(6)

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I. INTRODUCTION

At the outset of their brief, Plaintiffs specifically acknowledge that, in the face of an unprecedented health crisis, Moderna executed a contract with the U.S. Government and "then sold hundreds of millions of" doses of its life-saving COVID-19 Vaccine "***to the U.S. [G]overnment***." Resp. Br. at 1 (emphasis added). In that contract, the Government expressly authorized any allegedly infringing activities necessary for Moderna to deliver its vaccine. Under § 1498(a), that is enough to establish these doses were "use[d] or manufacture[d] for the United States" and Plaintiffs must file any infringement claim related to those doses in the Court of Federal Claims. Plaintiffs have not cited a single decision holding § 1498(a) does not apply to claims against products purchased by the Government and manufactured at the Government's request.

Instead, Plaintiffs make the remarkable claim that the Government did not purchase the vaccines "for the benefit of the U.S. government itself." Resp. Br. at 2. The Government does not enter into gratuitous contracts. COVID-19 is a contagious disease that threatened all aspects of governance, including the healthcare system and the economy. By purchasing the vaccines, the Government ensured an adequate supply for the military, other essential government workers, and enough of the population to curtail the pandemic. To be sure, individuals also benefited. But § 1498(a) does not demand that the Government be the ***sole*** beneficiary. Plaintiffs' position that § 1498(a) applies ***only*** under the improbable circumstances where the U.S. Government benefits, while its citizens do not, would eviscerate the entire purpose and intent of the statute. Every action the Government takes is supposed to benefit "the population as a whole." *Id*. at 1.

Semantic debates about whether the Government or citizens benefited are, in any event, beside the point. The government benefit test is a judicial gloss on § 1498(a)'s requirement that an allegedly infringing product must be "used or manufactured by or for the United States," and the case law uniformly holds that the U.S. Government need not be the ***sole*** beneficiary. Where the

U.S. expressly contracts for the manufacture of a product, the language of the statute makes clear it is for the benefit of the Government. That resolves Plaintiffs' direct infringement claims.

Plaintiffs' indirect infringement arguments are equally inconsistent with the text, purpose, and intent of § 1498(a). According to Plaintiffs, even if Moderna is not liable for direct infringement under § 1498(a), it is still liable for alleged indirect infringement by pharmacists who administered the vaccine and patients who received vaccine doses. Section 1498(a) is intended to encourage companies to enter into government contracts without fear of the burden, expense, and potential liability of patent infringement litigation. Contractors would take little comfort if the statute protected them from direct infringement claims but not indirect infringement claims when a member of the public uses the product acquired and distributed by the Government. For that reason, courts have consistently rejected similar arguments by litigants attempting to use indirect infringement to circumvent § 1498(a)'s protections. Moderna's partial motion should be granted.

II. ARGUMENT

A. Moderna Supplied Doses to the U.S. Government "for the Government"

The language in Moderna's contract with the Government is clear, direct, and emphatic that Moderna "manufactur[ed]" the relevant COVID-19 Vaccine doses "***for the United States Government***" (Ex. A at 19 (emphasis added); Resp. Br. at 13):

> The Department of Defense and Health and Human Services (HHS) require large scale manufacturing of vaccine doses in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19) ***for the United States Government*** (USG) and the US population.

Manufacturing and providing vaccine doses the Government contractually agreed to purchase is, by definition, "use or manufacture for the United States." 28 U.S.C. § 1498(a).

Despite the Government's express statement, Plaintiffs argue that the Government received no benefit or at least was not the sole beneficiary. Resp. Br. at 1–2. Plaintiffs resort to a contrived

distinction between benefits to the "U.S. population" and benefits to the Government. *Id.* at 10–12. The distinction is non-sensical and illusory, particularly in the context of an infectious virus like SARS-CoV-2 that "quickly spread[] around the world." Compl. ¶ 39.

Government actions that benefit the U.S. public as a whole also benefit the U.S. Government. At bottom, ***nothing*** in the Complaint negates that Moderna's sale and provision of the COVID-19 Vaccine was "for the Government." The allegations Plaintiffs cite (Resp. Br. at 12–15) simply recognize that individuals who received COVID-19 Vaccines ***also*** benefited. That does not deprive the Government of the benefits of its federally orchestrated mass vaccination campaign to ensure the health of the nation during a pandemic, in turn allowing the economy to reopen and recover, ensuring essential government services continued uninterrupted, and building the public's trust in the Government. *See John J. McMullen Assocs., Inc. v. State Bd. of Higher Ed.*, 268 F. Supp. 735, 739 (D. Or. 1967) (identifying "the safeguarding of public health" as being of "vital interest" to the Government under the first prong of § 1498(a)). It is astonishing that Plaintiffs would suggest that purchasing millions of vaccine doses to support a nationwide vaccination campaign in the midst of a pandemic is of no real benefit to the U.S. Government. Although that benefit is self-evident, Plaintiffs again ignore that it is expressly stated in the contract— "reduc[ing] SARS-CoV-2 transmission" and "mitigating the impact of COVID-19 on ***the nation*** and its people." *See* Op. Br. at 5, 11 (emphasis added, citing Ex. A at 19).

Unlike here, none of the cases Plaintiffs cite involved products purchased by the U.S. Government and manufactured at the Government's request. Plaintiffs rely on *Larson* for the proposition that "the government's payment for medical products for use by American citizens is not 'for the government' under section 1498(a)—even where the government 'funds or reimburses all of part of' their cost." Resp. Br. at 10 (quoting *Larson v. United States*, 26 Cl. Ct. 365, 369

(1992)). But the court's holding in *Larson* is not as sweeping as Plaintiffs suggest. As an initial matter, *Larson* did not involve ***any*** contract between the Government and the alleged infringer, let alone a contract with an authorization and consent clause. Instead, *Larson* involved healthcare providers who selected and purchased medical products from a supplier and later asked the Government for Medicare reimbursement. *See Larson*, 26 Cl. Ct. at 367–68. Here, the Government selected the vaccines, contracted to buy them directly from Moderna, and distributed them for the express benefit of mitigating the pandemic (in contrast to the scheme in *Larson* where any "types, models, or brand names of casts and splints" could be reimbursed). *See id.* at 367; Ex. A at 19.

In *Larson*, the Court concluded that "use of plaintiffs' casts and splints was for the benefit and convenience of the patient and provider, with no benefit to the government." 26 Cl. Ct. at 369. In contrast, Moderna's COVID-19 Vaccine has effects far beyond individual recipients, including prevention of widespread severe infections of ***others*** across the nation. Ex. A at 19. This disease-prevention benefit inures to the Government as well as the public by mitigating the health and economic effects of the COVID-19 pandemic, going far beyond the mere funding or reimbursement of individual "casts and splints" at issue in *Larson*.[2]

The other cases Plaintiffs cite are even further afield. In *Windsurfing Int'l*, the court rejected the tenuous theory that "the use of sailboards, chosen by an international body for use in Olympics to be held in the United States," was "use 'for' the" government because "running of the Olympics generally" was in the nation's interest. *Windsurfing Int'l, Inc. v. Ostermann*, 534 F. Supp. 581, 588 (S.D.N.Y. 1982). *Carrier Corp.* and *Riles* (*see* Resp. Br. 11–12) are equally inapplicable, as in all three cases, the Government had no interest in, and no contract for, the particular infringing

[2] As Moderna discussed in its opening brief (Op. Br. at 12), *Thermalon Industries, Ltd. v. United States*, is illustrative of the fact that the Government's purchase of vaccines is considered to be "for the general public welfare" (as indicated by the *cf.* citation). 34 Fed. Cl. 411, 420 (1995).

apparatus or method. *Carrier Corp. v. United States*, 534 F.2d 244, 247 (Ct. Cl. 1976); *Riles v. Amerada Hess Corp.*, 999 F. Supp. 938, 940 (S.D. Tex. 1998).

Moderna need not "refute the Complaint's allegations" that individuals ***also*** benefited. Resp. Br. at 13. While the manufacture or use must be "for the benefit of the government," *Advanced Software Design Corp. v. Fed. Rsrv. Bank of St. Louis*, 583 F.3d 1371, 1378 (Fed. Cir. 2009), even the cases Plaintiffs rely on recognize "[i]t is not necessary [for the Government] to be the sole beneficiary." *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014); *Advanced Software*, 583 F.3d at 1378 (same); *see also Sevenson Env't Servs., Inc. v. Shaw Env't, Inc.*, 477 F.3d 1361, 1365 (Fed. Cir. 2007) (holding § 1498(a) does not even require a contract's "primary purpose" be a government benefit). For that reason, several decisions have found § 1498(a) applies where others benefited ***in addition to*** the Government. *See Advanced Software Design*, 583 F.3d at 1378 (finding first prong met where fraud detection software provided "significant benefits to the United States, along with the financial benefits accruing" to banks); *Saint-Gobain Ceramics & Plastics, Inc. v. II-VI Inc.*, 369 F. Supp. 3d 963, 980 (C.D. Cal. 2019) (accused activities were "for the government," and it was "of no consequence that defendants also stood to benefit financially"). The only decision Plaintiffs cite suggesting otherwise is a 50-year-old district court case that predates the Federal Circuit and is out of step with that court's decisions. *See Molinaro v. Watkins-Johnson CEI Div.*, 359 F. Supp. 467, 470 (D. Md. 1973).

Finally, Plaintiffs mischaracterize Moderna's position when they claim that under Moderna's view, "every government-funded product used to advance any policy goal Congress articulates" would be subject to § 1498(a). Resp. Br. at 14. That is wrong. Moderna is not arguing § 1498(a) extends that far. A run-of-the-mill research grant does not—like here—include a contract requirement for the Government to actually purchase any product resulting from the

research effort. Moderna's contract is for the manufacture and supply of lifesaving products directly to the Government. The terms of that agreement, along with the clear, direct benefit to the Government (and the general public) stemming from Moderna's sale and provision of COVID-19 Vaccine doses, unmistakably meet the first prong of § 1498(a).

B. Moderna Had "the Authorization and Consent of the Government"

Plaintiffs do not deny that a FAR 52.227-1 authorization and consent clause satisfies the second prong of § 1498(a), as many other courts have found (Op. Br. at 12–14), nor do they dispute that this clause is expressly incorporated into Moderna's contract with the Government (Resp. Br. at 18–20).[3] Instead, Plaintiffs speculate that this clause "may have been modified" in the redacted parts of the publicly available contract, and ask the Court not to take judicial notice of it. *Id.*[4]

There is no need for unfounded speculation. Section I of the contract, which includes the authorization and consent clause incorporated by reference, contains ***no*** redactions. *See* Ex. A at 45–51. Any modifications to that clause would need to appear in that unredacted section. By regulation, FAR clauses incorporated by reference must be modified by "insert[ing] the changed wording directly below the title of the provision or clause . . ." FAR 52.104(b). No such modification appears in Section I. The redactions to other sections protect sensitive information such as individuals' names and locations for the delivery of the vaccine. Ex. A at 31, 36–39. The court in *D3D Techs., Inc. v. Microsoft Corp.* issued a § 1498(a) dismissal based on a government contract, like here, with an express authorization clause that had unrelated redactions of sensitive information. 2021 WL 2194601, at *2 (M.D. Fla. Mar. 22, 2021) ("The significance and

[3] Plaintiffs similarly do not dispute that the broader FAR 52.227-1 Alternate I authorization and consent clause is also incorporated and satisfies the second prong. *See* Op. Br. at 13 n.6.

[4] Contrary to Plaintiffs' assertion, Moderna asks the Court to take judicial notice of the contents of the contract (i.e., that it contains FAR 52.227-1), ***not*** the "truth of the content." Resp. Br. at 18.

authenticity of the IVAS contract is undisputed, and D3D references the contract in its Response."); Ex. C (redacted contract attached to motion to dismiss in *D3D Techs.*).

D3D Techs. is not an outlier. When resolving motions to dismiss, courts frequently take judicial notice of lightly redacted public records or publicly available documents. *See, e.g.*, *U.S. ex rel. Vampire Nation v. Citifinancial Mortg. Co.*, No. CIV A 06-936, 2007 WL 2142404, at *6 n.5 (W.D. Pa. July 9, 2007) (taking judicial notice of a mortgage agreement, applying 12(b)(6) standard, as a public record, although "redacted to delete social security numbers"), *report and recommendation adopted as modified*, No. CIV A 06-936, 2007 WL 2142410 (W.D. Pa. July 24, 2007); *M.D.C.G. v. United States*, No. 7:15-CV-552, 2016 WL 6638845, at *15 n.10 (S.D. Tex. Sept. 13, 2016) (analyzing 12(b)(6) dismissal, taking judicial notice of "publicly available (although partially redacted) report cited by Plaintiffs' response"), *aff'd in part*, 956 F.3d 762 (5th Cir. 2020). In the cases Plaintiffs cite, courts refused to take judicial notice when redactions appeared to conceal key facts or otherwise rendered it difficult to evaluate. Resp. Br. at 9, 19 (citing *IV Sols.*, *Delgado*, *Se. Ready Mix*, and *Phillips*). Neither concern applies here. Plaintiffs also cite *Leupold & Stevens, Inc. v. Lightforce USA, Inc.*, but that involved "significant questions of fact as to ***which*** contracts" contained Government authorization. 449 F. Supp. 3d at 1021 (emphasis in original). Here, there is no dispute that the contract incorporates FAR 52.227-1.

It makes no difference that the Government has not filed a statement of interest because one is unnecessary here. Resp. Br. at 19–20. The Government already stated its interest in any patent litigation over Moderna's COVID-19 Vaccine. That is the purpose of including a FAR 52.227-1 authorization and consent in the contract. Nothing more is needed. *See D3D Techs.*, 2021 WL 2194601, at *3 (granting 12(b)(6) motion under § 1498(a) without Government statement).

C. Plaintiffs' Indirect Infringement Allegations Are Subject to Section 1498(a)

Plaintiffs' argument that Moderna's alleged "inducement of, and contribution to,

infringement by healthcare providers and individual vaccine recipients" falls outside § 1498's protections is just as wrong and equally problematic. Resp. Br. at 15. Section 1498(a) is supposed to "relieve the contractor ***entirely*** from liability of ***every*** kind for the infringement of patents." *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 343 (1928) (emphasis added). The statute thus bars indirect infringement claims against government contractors "when such contractor is also liable for direct infringement and the United States government has assumed liability for such contractor's direct infringement pursuant to § 1498(a)." *Morpho Detection, Inc. v. Smiths Detection Inc.*, No. 2:11CV498, 2013 WL 5701522, at *4 (E.D. Va. Oct. 17, 2013). That makes sense. Protecting contractors from direct—but not indirect—infringement liability would do little to ease the fears of government contractors about the risk of costly patent litigation.

Here, Plaintiffs' direct and indirect infringement claims all stem from the same allegedly infringing product—Moderna's COVID-19 Vaccine—that was sold, manufactured, and distributed for the Government and with its authorization and consent. Therefore, consistent with "the clear directive in § 1498(a) as to the exclusive nature of the remedy provided therein," all of Plaintiffs' infringement claims against Moderna respecting COVID-19 Vaccine doses sold and provided to the Government (regardless of who ultimately administered or received those doses) are subject to § 1498(a) and must be dismissed. *Id.* at *5.

Were there any doubt, the contract makes clear the Government purchased the COVID-19 Vaccine doses so that they would be administered by healthcare providers to the general public. *See, e.g.*, Ex. A at 20 (clauses C.3.1.1.1 and C.3.1.1.3, reciting requirements to ensure the product is "available for use in target populations"); Compl. ¶¶ 115 (alleging that "[w]hen used as intended, the Accused Product infringes the '668 Patent's method claims."), 139 (same with respect to the '435 Patent). This should come as no surprise. Though there is no requirement that a product must

be both manufactured ***and*** used for the benefit of the Government, here the Government clearly and directly benefits from the COVID-19 Vaccine mitigating the public health, political, and economic effects of the pandemic—effects that do not accrue unless and until the vaccines are administered. Because the administration of government-purchased Moderna COVID-19 Vaccine doses leads to these government benefits, the allegedly infringing act of administering the vaccines is "for the Government" and claims for Moderna's alleged indirect infringement must be brought against the United States in the Court of Federal Claims. *See Astornet Techs. v. BAE Sys., Inc.*, 802 F.3d 1271, 1277–78 (Fed. Cir. 2015) (indirect infringement claims are barred by §1498(a) where the underlying act of direct infringement is performed by or for the Government).

D. Moderna's Motion Is Not "Premature"

Plaintiffs' argument that § 1498(a) defenses must wait until summary judgment is meritless. Courts regularly dismiss claims under § 1498(a) that should have been filed in the Court of Claims against the Government. *See, e.g.*, *Astornet*, 802 F.3d at 1276, 1283 (affirming motion to dismiss under § 1498(a)); *Japan Airlines*, 769 F.3d at 1363 (same); *D3D Techs.*, 2021 WL 2194601, at *1 (granting motion to dismiss under § 1498(a)). The Federal Circuit's decision in *Toxgon Corp. v. BNFL, Inc.*, 312 F.3d 1379, 1380 (Fed. Cir. 2002), does not cast doubt on these decisions. *Toxgon* merely held § 1498 is not a jurisdictional defense that can be raised in a Rule 12(b)(1) motion, *id.* at 1382, and subsequent Federal Circuit decisions have affirmed Rule 12(b)(6) dismissals based on § 1498(a) defenses. *See Astornet*, 802 F.3d at 1276, 1283; *Japan Airlines*, 769 F.3d at 1363.

The only restriction on raising an affirmative defense in a motion to dismiss is that the defense must appear on the "face" of the pleadings and anything subject to judicial notice. *ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 (3d Cir. 1994); *Omega Advisors, Inc. v. Fed. Ins. Co.*, No. CIV.A. 10-912 JAP, 2010 WL 4941457, at *5 (D.N.J. Nov. 30, 2010). Moderna's § 1498 defense

is evident from the unambiguous terms of Modern's contract with the Government—none of which are contradicted by allegations in the Complaint. Rule 12(b)(6) allows for the assertion of such a defense at the pleading stage.

Plaintiffs claim that dismissal is unjustified because "[n]o count would be dismissed" and it "would not streamline" the case. Resp. Br. at 4, 18. Whether Moderna's § 1498 defense would eliminate an entire count is irrelevant. Courts can and do dismiss parts of a Complaint. *See, e.g.*, *D3D Techs.*, 2021 WL 2194601, at *5; *Merrell & Garaguso, Inc. v. Sunoco, Inc.*, No. Civ.A. 04-1770, 2004 WL 1849705, at *2–3 (E.D. Pa. 2004). Plaintiffs cannot do an end-run around § 1498 by simply lumping immune sales together with other sales. As for discovery, Plaintiffs have previewed that they intend to subject Moderna to unnecessary and burdensome discovery on the "negotiations" and "communications" relating to the contract, and "how the purchased doses were distributed and to whom." Resp. Br. at 17. None of this would be necessary if claims related to those sales are dismissed.[5] In fact, no discovery on infringement or damages would be needed for the batches containing the "more than 200 million doses" supplied under the contract. Compl. ¶ 51.[6] Streamlining discovery in this way would further § 1498(a)'s goal of sparing government contractors from "expensive litigation." *TVI Energy Corp. v. Blane*, 806 F.2d 1057, 1059–60 (Fed. Cir. 1986); *see also Richmond Screw*, 275 U.S. at 342–43 (explaining that § 1498(a) was adopted in part based on concerns that government contractors "are exposed to expensive litigation").

III. CONCLUSION

Moderna respectfully requests that the Court grant its partial motion to dismiss.

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[5] *Advanced Software Design* and *Madey* are inapposite because the Government was not a party to the contracts that did not include an authorization and consent clause. *See Advanced Software Design*, 583 F.3d at 1373–74, 1377; *Madey v. Duke Univ.*, 307 F.3d 1351, 1359 (Fed. Cir. 2002).

[6] Partial dismissal would also ensure that the Government could litigate the "reasonable and entire compensation" in the Court of Federal Claims for any alleged infringement. 28 U.S.C. § 1498(a).

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June 24, 2022

CERTIFICATE OF SERVICE

I hereby certify that on June 24, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on June 24, 2022, upon the following in the manner indicated:

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